

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Schwarz Pharma, Inc., Schwarz Pharma
AG, and Warner-Lambert Company LLC,¹

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

**MEMORANDUM OPINION
AND ORDER**
Civil No. 05-832 ADM/AJB

Laura J. Hein, Esq., Gray, Plant, Mooty, Mooty & Bennett P.A., Minneapolis, MN, and Brian M. Poissant, Jones Day, New York, NY, on behalf of Plaintiffs.

Barbara P. Berens, Esq., Kelly & Berens, P.A., Minneapolis, MN, and P. Branko Pejic, Esq., Greenblum & Bernstein, P.L.C., Reston, VA, on behalf of Defendant.

I. INTRODUCTION

This matter is before the undersigned United States District Judge on Defendant's Appeal ("Appeal") [Docket No. 35] of Magistrate Judge Arthur J. Boylan's Pretrial Scheduling Order ("Order") [Docket No. 34].² The Order established a September 1, 2006 deadline by which all dispositive motions shall be served, filed and heard. The Order also struck as premature

¹ In the caption of the Complaint, Plaintiffs' misspell "Schwarz Pharma, Inc." as "Schwartz Pharma, Inc." Schwarz is spelled correctly throughout the remainder of the Complaint and the caption of this Order reflects the proper spelling.

² Plaintiffs' Response Brief [Docket No. 40] was untimely under L.R. 72.2(a) since it was received more than ten days after Plaintiffs were served with a copy of Defendant's Objections. Because Defendant did not object to the timeliness of the Response Brief and because it does not alter the Court's analysis, Plaintiffs' Response Brief will be considered. Defendant subsequently filed a reply letter [Docket No. 43], to which Plaintiffs also responded [Docket No. 45], although the Local Rules do not provide for such communications. Again, it is unnecessary for the Court to rule on their appropriateness since they do not alter the outcome of the instant motion.

Paddock Laboratories, Inc.’s (“Paddock” or “Defendant”) previously filed Motion for Summary Judgment [Docket No. 12]. The Motion was scheduled to be heard on September 14, 2005. The Order also denied as moot Defendant’s Motion to Stay Discovery [Docket No. 21], which had been scheduled to be heard on August 9, 2005. Paddock argues the Order is clearly erroneous, contrary to law, and constitutes an abuse of discretion. For the reasons set forth below, Paddock’s Appeal is denied and the Order is affirmed.

II. BACKGROUND

Schwarz Pharma, Inc., Schwarz Pharma AG, and Warner-Lambert Company LLC (collectively, “Schwarz Pharma” or “Plaintiffs”) are owners or licensees of United States Patent No. 4,743,450 (the “‘450 patent”), which, they allege, claims pharmaceutical compositions composing certain Angiotensin-Converting Enzyme (“ACE”) inhibitors, including moexipril hydrochloride. Compl. [Docket No. 1] ¶¶ 9-12. On March 17, 2005, Plaintiffs received a Notification Letter stating Paddock had submitted amended new drug application (“ANDA”) 77-536 to the FDA seeking marketing approval for tablets containing 7.5 mg and 15 mg of moexipril hydrochloride (“Moexipril Tablets”). *Id.* ¶ 13. In their Complaint, Plaintiffs allege “Paddock’s submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Moexipril Tablets prior to the expiration” of the “‘450 patent” will constitute infringement of the patent. *Id.* ¶ 16. This litigation ensued.

III. DISCUSSION

A. Standard of Review

The standard of review for appeals of a magistrate judge’s order on nondispositive pretrial matters is extremely deferential. The district court must affirm an order by a magistrate

judge unless it is “clearly erroneous or contrary to law.” See D. Minn. LR 72.2; see also Banbury v. Omnitrition Int’l Inc., 818 F. Supp. 276, 279 (D. Minn. 1993). “A finding is ‘clearly erroneous’ when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” Chakales v. Commissioner of Internal Revenue, 79 F.3d 726, 728 (8th Cir. 1996).

B. Objections

Paddock argues the Order is clearly erroneous, contrary to law, and constitutes an abuse of discretion on the following grounds: (1) the Order delays resolution of this case in contravention of the purpose of the Hatch-Waxman Act; (2) Rule 56(b) of the Federal Rules of Civil Procedure does not place any temporal restrictions on summary judgment motions; and (3) the Order unnecessarily increases the burden and expense on the Court and the parties.

1. Hatch-Waxman Act

Paddock first argues the striking of its expedited summary judgment motion violates the fundamental purpose of the Hatch-Waxman Act.³ Paddock quotes legislative history to support its argument that the purpose of the Hatch-Waxman Act is to allow affordable, generic drugs to reach the market more quickly. See Def.’s Mem. of Law [Docket No. 36] at 2-3, 10. Paddock argues the Order frustrates this purpose by striking its expedited summary judgment motion.

The Hatch-Waxman Act is designed to permit generic medication to reach the market more quickly by streamlining the FDA’s approval process. Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323, 1325-27 (Fed. Cir. 2001). Consequently, the Act created the ANDA procedure

³ The Hatch-Waxman Act is the colloquial name for the Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355.

so the FDA could expedite approval for generic drugs. Id. Paddock fails to cite any provision of the Act or authority interpreting the Act to show it requires, or even contemplates, that district courts entertain expedited summary judgment of pharmaceutical patent infringement claims. The focus of the Act is directed towards the regulatory process rather than the litigation context. Therefore, the Order's decision to strike Paddock's Summary Judgment Motion is clearly not erroneous or contrary to the Hatch-Waxman Act.

2. Lack of Temporal Limitations in Fed. R. Civ. P. 56(b)

Paddock next argues the Order is clearly erroneous and contrary to law because Rule 56(b) of the Federal Rules of Civil Procedure does not impose a temporal limitation on motions for summary judgment. Paddock argues it is not challenging the validity or enforceability of the '450 patent, only whether it infringed the patent. Paddock also claims this task is made simpler since the relevant claims have already been construed and Plaintiffs are estopped from asserting the doctrine of equivalents by prior litigation. Finally, Paddock argues Plaintiffs possess all information necessary, such as the ANDA and product samples, to respond to Paddock's summary judgment motion. As a result, Paddock claims discovery is unnecessary and expedited summary judgment is appropriate. In support of this position, Paddock cites one patent case that was decided before discovery was commenced. See Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 2001 WL 1035713, at *5 (N.D. Ill. Sept. 4, 2001), aff'd in part and vacated in part, 347 F.3d 1314 (Fed. Cir. 2003), cert. denied, 540 U.S. 1184 (2004).

"As a general rule, summary judgment is proper 'only after the non-movant has had adequate time for discovery.'" Iverson v. Johnson Gas Appliance Corp., 172 F.3d 524, 529 (8th Cir. 1999) (citation omitted). Although it is not necessary that discovery be completed before

summary judgment is appropriate, the parties initial disclosures are not due until August 31, 2005.⁴ Pls.' Response Brief [Docket No. 40] at 4. Paddock makes several assertions concerning the simplicity of the instant case and the appropriateness of expedited summary judgment. Schwarz Parma disagrees with Paddock's assessment and dedicates a significant portion of its response brief to describing the information it seeks to obtain in discovery. Id. at 6-8. Consequently, it would appear that at least initial disclosures are appropriate.

Even assuming the truth of Paddock's assertions, they do not present any legal basis for holding the Order is clearly erroneous or contrary to law. Courts enjoy broad discretion over scheduling matters. Williams v. Lomen, 81 Fed. App. 871, 873 (7th Cir. 2003) ("a district court has substantial discretion in managing its schedule and docket"). Although Rule 56(b) does not contain temporal limitations on summary judgment, neither does it require the Court entertain a summary judgment motion at this extremely early stage of litigation. Likewise, the court in Deering Precision Instruments found expedited summary judgment was permissible when the only outstanding discovery requests concerned extrinsic evidence not relevant to the claim construction issues before the court. 2001 WL 1035713, at *5. Such a fact-dependent holding does not, by itself, render the Order at issue in the instant case clearly erroneous or contrary to law.

Finally, Paddock did not submit its ANDA for FDA approval until January 18, 2005. The parties debate the length of time that generally elapses before the FDA grants final approval

⁴ In the absence of a Rule 62(f) affidavit from the opposing party showing the need for and relevance of further discovery, summary judgment is appropriate before the close of the discovery period. See Carman v. McDonnell Douglas Corp., 114 F.3d 790, 792 (8th Cir. 1997). The Order permits parties to submit summary judgment motions before the close of discovery with the leave of the court. Order at 10.

to an ANDA. Paddock claims the median final ANDA approval time is 15.7 months while Schwarz Pharma claims the average final ANDA approval time is approximately 25 months. See Def.'s Reply Brief; Pls.' Resp. to Def.'s Reply Brief. Even assuming Paddock's estimate of 15.7 months is correct, its ANDA would not receive final approval until sometime in May of 2006.⁵ Given the FDA approval schedule, there is no need to expedite summary judgment in the instant matter. If Paddock's ANDA receives final approval, or even tentative approval, before the close of discovery, Paddock may petition the Court for leave to file a summary judgment motion.

3. Judicial Efficiency

Finally, for the reasons discussed in the preceding section, Paddock contends expedited summary judgment is also appropriate because it would save both the parties and the Court unnecessary burden and expense. As previously noted, Courts have broad discretion in matters of scheduling. Williams, 81 Fed. App. at 873. Although judicial efficiency is a goal of this Court, it does not provide a basis for determining that the Order is clearly erroneous or contrary to the law.

For the reasons set forth above, Defendant's appeal is denied and Judge Boylan's Order is affirmed.

⁵ Discovery must be completed by end of June 2006.

III. CONCLUSION

Based upon the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. The Order [Docket No. 34] is **AFFIRMED**; and
2. Defendant's Appeal of the Order [Docket No. 35] is **DENIED**.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: September 1, 2005.